

### **REMARKS**

Applicants request entry and consideration of the amendment and remarks submitted herein. Applicants traverse all objections, rejections and assertions made by the Examiner. Claims 1-35 are currently pending in this application.

As a preliminary matter, Applicants note that the Examiner indicated attachment of PTO-1449s, Paper Nos. 2 and 4, but Applicants received an initialed and dated copy of only the 1449 filed March 20, 2002, Paper No. 2. Applicants respectfully request that the Examiner return an initialed and dated copy of PTO-1449 filed December 11, 2002, Paper 4, with the next communication from the Office.

#### **Objection to the Specification**

The specification was objected to for referencing "elongate shaft" at page 3, line 6 with an incorrect reference numeral. Applicants have amended the specification at page 3, line 6 as suggested by the Examiner. Withdrawal of the rejection is respectfully requested.

#### **Rejections under 35 U.S.C. § 102(b)**

Claims 1, 2 17-20 and 21 are rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,662,621 to Lafontaine. The Examiner asserts that Lafontaine teaches a stainless steel elongate core wire having an elastic limit and a polymer jacket surrounding a distal portion of the core wire having an elastic limit, with the jacket being more stiff than the distal portion of the core wire it surrounds so that when deformed into a shape within the elastic limit of the metal and beyond the elastic limit of the polymer, the tip retains the shape in that once the polymer jacket acquires its stiff, memory retention shape, the core wire has the shape provided by the jacket as claimed. The Examiner further asserts that with regard to claims 17-19 Lafontaine

discloses the claimed method including deforming the polymer jacket and the core wire into a shape; heating the deformed polymer jacket to a temperature at or above the glass transition temperature of the shape memory polymer; and cooling the jacket to form and maintain different shapes including the original shape. Applicants disagree.

Lafontaine fails to disclose at least two elements of claims 1, 2 17-20 and 21. Lafontaine fails to disclose any structure of a guidewire. Lafontaine also fails to disclose a polymer jacket being stiffer than the portion of the core wire it surrounds.

The pending claims are all directed to guidewires. Lafontaine is solely directed to catheters. The FIELD OF THE INVENTION for Lafontaine states:

The present invention relates to guide catheters and diagnostic catheters used in medical catheterization procedures. In particular, the present invention relates to an improved guide or diagnostic catheter having a simple catheter design, which is capable of being selectively curved or shaped to a desired form during catheter procedures.

(Column 1, lines 5-10.) In addition, Lafontaine does not disclose any guidewire structure and only claims catheter structures. Thus, Lafontaine fails to anticipate any of the pending guidewire claims 1, 2 17-20 and 21.

The pending claims all require a polymer jacket being stiffer than the portion of the core wire it surrounds. Lafontaine never discloses the stiffness of the catheter core relative to the stiffness of the catheter sheath. Applicants assert that the catheter core of Lafontaine is stiffer than the catheter shaft based on the specification of Lafontaine. Lafontaine states that the catheter core shapes the catheter shaft. Lafontaine states that the guide catheter's shape is changed while within the patient's vascular system.

Lafontaine repeatedly states that the catheter core provides the mechanical stimulus to change the shape of the catheter shaft. At column 5, lines 1-7 Lafontaine states:

The present invention includes a core which provides structural support to the guide catheter for steering the guide catheter through a patient's vascular system, while providing the memory retention stimulus to the guide catheter for shaping the guide catheter during a catheterization procedure.

At column 5, lines 60-62 Lafontaine states:

Core 24 provides the stimulus to guide catheter 22 for transitioning guide catheter 22 between a soft, straight state and a pre-shaped, relatively stiff, memory retention state.

At column 6, lines 27-40 Lafontaine states:

Additionally, deflection of the core 24 for shaping guide catheter 22 while it is in a soft state may be controlled at control unit 58 by mechanism 66. In the preferred embodiment, mechanism 66 is a pull wire mechanism which may selectively control deflection of core 24, by methods as disclosed in U.S. Pat. No. 5,383,923 to Webster which is herein incorporated by reference.

Additionally, it is also recognized that other mechanisms may be used for deflection of core 24 to change the shape of the guide catheter 22. For example, it is recognized that hydraulic cylinders, mechanical lead screws, and similar devices may be used to supply the mechanical stimulus to change the shape of the core 24 while the core 24 is positioned within the patient's vascular system.

At column 7, lines 34-39 Lafontaine states:

Core 24 may be re-inserted for softening guide catheter 22 to re-form guide catheter 22 for a new coronary position, such as switching the distal end 36 of guide catheter 22 from the left coronary artery to the right coronary artery.

Thus, it is clear that the Lafontaine catheter core shapes the catheter shaft. Thus, the catheter shaft cannot be assumed to be stiffer than the catheter core of Lafontaine.

In addition, Lafontaine states that the guide catheter's shape is changed while within the patient's vascular system. At column 7, lines 59-65 Lafontaine states:

It is recognized that other methods may be used for changing guide catheter 22 between a relatively soft, ductile state and a

relatively stiff shape-memory state, such as softening by heat, light, or the use of chemicals. In each method, the shape and stiffness of guide catheter 22 may be changed while the guide catheter 22 is positioned within a patient's vascular system.

Thus, it is clear that the Lafontaine catheter core shapes the catheter shaft. Thus, the catheter shaft cannot be assumed to be stiffer than the catheter core of Lafontaine.

Therefore, for at least these reasons, pending claims 1, 2 17-20 and 21, and those dependent therefrom, are patentable over Lafontaine. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **Rejections under 35 U.S.C. § 103(a)**

Claims 3, 4, 22 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,662,621 to Lafontaine in view of U.S. Patent No. 5,772,609 to Nguyen et al. ("Nguyen"). The Examiner asserts that Nguyen teaches forming the elongate core wire of either stainless or a super elastic metal comprising a nickel titanium alloy as claimed. The Examiner further asserts that selection of a superelastic material is within the skill in the art. Applicants disagree.

Nguyen fails to remedy the deficiencies of Lafontaine as described above and claim 3, 4, 22 and 23 further distinguish over the prior art. Therefore, Applicants assert claims 3, 4, 22 and 23 are patentable over Lafontaine in view of Nguyen. Applicants respectfully request reconsideration and withdrawal of the rejection.

Claims 5-16 and 24-35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,662,621 to Lafontaine in view of U.S. Patent No. 6,485,458 to Takahashi et al. ("Takahashi"). The Examiner asserts that Takahashi teaches shape memory polymer surrounding a core wire wherein the polymer consists of poluorbornen, styrene-butadiene,

polyurethane, polyisoprene, polyester, polyester, polyolefin, acrylic and styrene-acrylic. The Examiner further asserts selection of a shape memory polymer is within the skill in the art. Applicants disagree.

Takahashi fails to remedy the deficiencies of Lafontaine as described above and claim 5-16 and 24-35 further distinguish over the prior art. Therefore, Applicants assert claims 5-16 and 24-35 are patentable over Lafontaine in view of Takahashi. Applicants respectfully request reconsideration and withdrawal of the rejection.

In view of the above, it is respectfully submitted that claims 1-35 are patentable over the cited references. Favorable reconsideration is requested.

### CONCLUSION

In view of the above, Applicants respectfully request withdrawal of the rejections and allowance of the claims. Should the Examiner feel a telephone interview would be helpful in advancing this case to allowance, Applicants invite the Examiner to contact their representative at the number listed below.

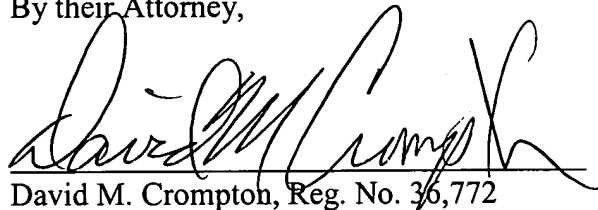
Respectfully submitted,

Stephen Griffin et al.

By their Attorney,

Date: \_\_\_\_\_

9/4/03



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